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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/441,443	05/15/95	HOUGHTON	K 0063.024

18M1/1218

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EXAMINER

ZEMAN, M

ART UNIT

PAPER NUMBER

1815

DATE MAILED: 12/18/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 9/23/97 + 11/25/97

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire — 3 — month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 40-52 is/are pending in the application.

Of the above, claim(s) 49-52 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 40-48 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 10

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

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DETAILED ACTION

1. Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's first submission after final filed on 9/23/97 has been entered.
2. New claims 40-52 are drawn to at least one new invention not previously prosecuted in any parent application, and these new claims do not fall within the restriction made in the parent case 08/307,273.

Election/Restriction

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 40-48, drawn to antisense polynucleotides, classified in class 536, subclass 24.5.
 - II. Claims 49-51, drawn to a delivery system for an antisense polynucleotide and methods of treating a patient by administering that antisense polynucleotide, classified in class 514, subclass 44.
 - III. Claim 52, drawn to a method of inhibiting viral replication, classified in class 435, subclass 7.1.

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4. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II/III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case antisense polynucleotides can be used as probes, and primers for PCR.

Inventions II and III are distinct as the method of invention II require a composition comprising the antisense polynucleotide and a liposome, while invention III uses solely the polynucleotide, and is not necessarily administered to a patient.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Ken Goldman on 12/9/97 a provisional election was made with traverse to prosecute the invention of Group I, claims 40-48. Affirmation of this election must be made by applicant in responding to this Office action. Claims 49-52 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

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named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Double Patenting

8. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

9. Claims 40-45 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 24-57 of copending allowed Application No. 08/040,564. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Although the conflicting claims are not identical, they are not patentably distinct from each other because the oligonucleotides of the '564 application fulfill the limits of claims 40-45, as an oligonucleotide can be used as an antisense nucleotide, and an antisense polynucleotide can be used as an oligonucleotide. The chemical compositions are the same, and the recitation of "antisense" is merely a statement of intended use.

Claim Rejections - 35 USC § 112

10. Claims 40-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of claim 40 is vague and confusing. An antisense nucleotide is defined in that it hybridizes with the sense strand of a DNA sequence, ie the coding strand (therefore the oligo is complementary to the coding sequence). Claim 40 sets forth that the antisense polynucleotide can be complementary to an HCV genome, or complementary to the complement-effectively making it sense strand, and therefore not an antisense oligonucleotide.

Nothing within claims 40-45 sets the claimed antisense polynucleotides apart from oligonucleotides used as probes, or PCR primers. Therefore, the term "antisense" would appear to be a statement of intended use, and not a patentably distinct feature of the invention.

11. Claims 40-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 40-48 are drawn to antisense oligonucleotides of varying lengths which may have altered bonds, or chemical entities attached to them. Claims 40-44 set forth lengths from 8 to 20 nucleotides for the antisense oligonucleotides. The specification, as filed, does not point out oligonucleotides of 8, 10, 12, 15 or 20 nucleotides that would be suitable for use as antisense

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polynucleotides. There is no direction as to which sequences should be selected from the approximately 9Kb of HCV sequence. There is no teaching as to which portions of the HCV genome would be susceptible to an antisense blockage and therefore a suitable region from which the polynucleotide could be selected, nor is there an indication as to what length of oligonucleotide is preferred. There is no recitation of particular sequences of polynucleotides useful in the practice of the invention. It is apparent that the polynucleotides may comprise other, non-HCV sequences, as long as there is a stretch of HCV sequence within, which further broadens the scope of the claims. The very large number of potential polynucleotides covered by the scope of the pending claims is an invitation to experiment with the 9000+ nucleotides of HCV-1 and any other HCV or non-HCV sequence, to find polynucleotides which are capable of acting as antisense polynucleotides in the practice of the invention.


12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 8:00 am and 5:30 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-4311.

The fax number for this Art Unit is (703) 305-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


MICHAEL P. WOODWARD
PRIMARY EXAMINER
GROUP 1800